K042370

DEC 17 2004

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Toray Industries (America), Inc.
461 Fifth Avenue, 9th Floor
New York, NY 10017
Telephone: (212) 697-8150
Contact person: Mr. Koji Hagimoto, Director, Medical and Pharmaceutical

Date of Summary: November 12, 2004

Device Name: TORAYGUIDE™ Guidewire

Device Classification Name: Catheter Guide Wire (74 DQX); 21 CFR, Part 870.1330

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate device is the Guidewire (K982559) manufactured by Galt Medical Corporation, determined to be substantially equivalent to a legally marketed (preAmendment) device on February 1, 1999.

Device Description: The TORAYGUIDE™ Guidewire is manufactured of 304 stainless steel, which is consistent with guidewires presently in commercial distribution and with the same intended use. The device diameter is 0.65 mm, and is supplied in lengths ranging from 175 to 230 cm. The guidewire has a spring core at the distal end, also of stainless steel. The device is ethylene oxide sterilized and intended for single use only.

Intended Use: The TORAYGUIDE guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the heart and peripheral vasculature. The device is not intended for use in the coronary arteries.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The TORAYGUIDE Guidewire has the same indications for use and is otherwise technically identical to the legally marketed predicate device.

Performance Data: Applicable testing was conducted on the TORAYGUIDE guidewire in accordance with the FDA guidance. All samples met the acceptance criteria. The test results establish that the TORAYGUIDE Guidewire possesses performance characteristics that make it acceptable for its intended use.

Conclusion: The information and data provided in this 510(k) Notification establish that the TORAYGUIDE Guidewire is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2004

Toray Industries (America), Inc
c/o Ms. Lisa S. Jones
Regulatory Affairs Consultant
461 Fifth Avenue, 9th Floor
New York, NY 10017

Re: K042370
Torayguide™ Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: November 12, 2004
Received: November 16, 2004

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042370

Device Name: TORAYGUIDE Guidewire

Indications For Use: The TORAYGuide guidewire is intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within the heart and peripheral vasculature. The device is not intended for use in the coronary arteries.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042370